

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR
WARMING DEVICES PRODUCTS
LIABILITY LITIGATION

MDL No. 15-2666 (JNE/FLN)

This Document Relates To:
Nugier, 16-cv-4246

**MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION TO
COMPEL AGAINST THE MIAMI
VETERANS ADMINISTRATION
MEDICAL CENTER**

Defendants seek to compel third-party discovery from the Miami Veterans Administration Medical Center (“Miami VA”) in one of the two bellwether cases that has been prioritized for discovery by the Court, *Nugier* (16-cv-4246). The fact discovery cutoff for *Nugier* is October 16, 2017. (ECF No. 633, ¶ 14.)

John Nugier, the plaintiff, underwent a total knee arthroplasty and subsequent treatment for infection at the Miami VA. Plaintiffs allege that a Bair Hugger system was used in Mr. Nugier’s surgery and caused his infection. After repeated contacts to the Regional Counsel for the Miami VA to request and arrange for depositions and a third-party request for documents (see Meet-and-Confer Certificate), Defendants issued subpoenas to the Miami VA on August 16 and August 21 for documents and for the depositions of a Rule 30(b)(6) designee and two important treating physicians. The document requests and deposition topics accompanying the subpoenas relate to the central issues in the case, including the use of the Bair Hugger system at the Miami VA, infection control procedures in place at the time of Mr. Nugier’s surgery, and the details and

circumstances of Mr. Nugier’s surgery – critical information for analyzing potential causes of his alleged post-surgery infection.

Despite accommodations repeatedly offered by Defendants, the Miami VA has categorically refused to produce any documents or offer any witnesses in response to Defendants’ third-party discovery requests. The Miami VA rests entirely on boilerplate objections and the protections of the “*Touhy* regulations” that provide certain protections to the VA and its medical providers but do not insulate them entirely from discovery. Defendants request that this Court order the Miami VA to respond in full to Defendants’ discovery by producing responsive documents and presenting the requested witnesses.

The problems Defendants face in getting necessary discovery from the Miami VA are not problems of Defendants’ own making: *Nugier* was selected as a bellwether by Plaintiffs. Thus, if Defendants are not allowed to take this vital discovery on Mr. Nugier’s medical treatment, they request in the alternative that his case be de-designated as a bellwether. There are, of course, many other cases in this MDL that do not involve the discovery obstacles presented here by the Miami VA.

RELEVANT FACTUAL BACKGROUND

A. Defendants Have Sought Discovery from the Miami VA that is Highly Relevant to the Issues in the *Nugier* Case, and Have Offered to Accommodate the Busy Schedules of Its Medical Practitioners.

Defendants seek highly relevant evidence from the Miami VA – evidence that is critical to defendants’ defense.

First, Defendants seek the deposition of Dr. Henry Bernstein, an orthopedic specialist who was the attending physician and surgeon during Plaintiff’s total knee

replacement on March 7, 2012, and the two subsequent revision surgeries on July 25, 2012 and October 28, 2012, to address Plaintiff's prosthetic joint infection and revise his total knee arthroplasty, respectively. Dr. Bernstein was the only surgeon involved in all three procedures and, accordingly, his knowledge cannot be obtained through other witnesses. (Hulse Decl. Ex. 1, 8/16/17 letter re: Bernstein.)

Second, Defendants seek the deposition of Dr. Paola N. Lichtenberger. Dr. Lichtenberger is an infectious-disease specialist who was an attending infectious disease consultant during Mr. Nugier's hospitalization at the Miami VA that commenced on July 23, 2012. Dr. Lichtenberger was the attending physician for the initial infectious-disease consult performed on July 27, 2012, at which time the diagnosis of prosthetic joint infection was made and a plan of treatment commenced. (Hulse Decl. Ex. 2, 8/16/17 letter re: Lichtenberger.) His knowledge cannot be obtained through other non-VA witnesses.

Third, Defendants see a 30(b)(6) deposition on subject matters important to Defendants' defense of the *Nugier* case (Hulse Decl. Ex. 3, 8/21/17 letter re: Rule 30(b)(6) notice and document requests):

Topic 1: Communications between the Miami VA Medical Center and 3M or Arizant related to the Bair Hugger are relevant to determine the knowledge and experience of the Miami VA Medical Center concerning the use of the Bair Hugger system.

Topic 2: Communications, if any, of the Miami VA Medical Center to staff and affiliated medical practitioners concerning any possible risk of infection associated

with the Bair Hugger and other forced-air patient warming systems is central to the issues being litigated by the parties – whether Plaintiff’s prosthetic joint infection was caused by use of the Bair Hugger system, and whether any Health Care Providers have ever considered forced-air warming systems as a potential cause of prosthetic joint infection.

Topic 3: Topic 3 seeks communications and interactions with Dr. Scott Augustine, and associated corporations and organizations. As this Court is well aware, Dr. Augustine has campaigned against forced-air warming systems, including the Bair Hugger, under the theory that such systems increase the risk of prosthetic joint infections. If the Miami VA Medical Center’s knowledge and use of the Bair Hugger system, or practices related to arthroplasty surgery, have been affected by any communications from Dr. Augustine or those entities identified in Topic 3, that information must be known by Defendants to adequately defend Plaintiff’s claims concerning the Bair Hugger system in this particular case.

Topics 4, 5, 6, 11: In addition, information regarding infection control policies, protocols, and procedures and infection-control rates is critical to the question of causation. Defendants maintain that the Bair Hugger system was not a cause of Mr. Nugier’s infection, and that such infection is a well-known and long-recognized risk of joint-replacement surgery, with or without the use of a forced-air warming system. Policies related to cleaning, disinfecting, and infection control (Topics 4 and 6), service and maintenance of the Bair Hugger system (Topic 5), and infection

rate data (Topic 11) are needed to establish that prosthetic joint infection occurs despite the presence of appropriate practices and policies, and proper medical care, and regardless of the use of a patient warming system such as the Bair Hugger.

Topics 7, 8, 9: Information specific to the configuration of the operating room and personnel involved in Plaintiff's total knee arthroplasty is also important to the issue of causation. Despite appropriate policies, procedures, and protocols, and appropriate care by medical personnel, there are multiple potential sources for Plaintiff's prosthetic joint infection that are unrelated to the Bair Hugger system. It is necessary to know the number and identities of the personnel involved in the total knee arthroplasty (Topic 8), the clothing and supplies utilized by those individuals (Topic 9), and specific information concerning the Bair Hugger and the specific operating room used for the procedure (Topic 7).

Topic 10: Factual information regarding the HVAC system in the operating room is critical to the opinions of case-specific expert witnesses, who will comment on whether use of the Bair Hugger affected the flow of air in and around the surgical site. Expert witnesses will need to recreate, to the greatest extent possible, details of the operating room to educate the jury regarding causation.

B. The Miami VA Has Asserted Boilerplate Objections to Producing Documents and Witnesses, and Has Refused to Even Acknowledge the Accommodations Offered by Defendants.

The "*Touhy* regulations" provide some protection against an undue burden for the VA medical practitioners in responding to discovery in limited circumstances. 38 C.F.R. §

14.804. Mindful of the *Touhy* regulations (discussed below in further detail), Defendants repeatedly offered to accommodate the schedules of the Miami VA's witnesses, stating: "[W]e are agreeable to flexibility in the date and start times of any depositions, and are happy to make accommodations outside of business hours as necessitated." (Hulse Decl. Exs. 1-3.) However, on August 24, 2017, the Miami VA responded with a boilerplate letter stating that it would not produce documents or present witnesses in response to Defendants' discovery.

Citing the *Touhy* regulations, the Miami VA stated: "[W]e believe that compliance with the subpoena would require spending the time and money of the United States for private purposes and would unjustifiably divert VA personnel from their official duties. The providers requested for deposition are essential to ongoing care of veterans in a timely manner. The subpoena demand is unduly burdensome." (Hulse Decl. Ex. 4, Miami VA letter.) The Miami VA did not explain which requests specifically were burdensome or suggest any way to narrow them.

The Miami VA further objected, without detail or explanation, that Defendants' discovery would require the Miami VA to "provid[e] opinion or expert testimony concerning official VA subjects" and would unduly favor one litigant over another. (*Id.*) Finally, the Miami VA objected that Mr. Nugier's records could not be disclosed without the consent of Mr. Nugier or a court order. The significance of this objection was entirely unclear, given that the Miami VA had *already disclosed* Mr. Nugier's medical records pursuant to a records authorization. (*Id.*) As of the date of this motion, the Miami VA has failed to provide any further detail or clarification of its objections.

ARGUMENT

A. This Court has Authority to Rule on this Dispute.

As a threshold matter, this Court has the authority to enforce Defendants’ subpoenas to the Miami VA. Although Rule 45 of the Federal Rules of Civil Procedure generally requires enforcement in the jurisdiction where compliance is sought, this Court may properly address the issue under the authority conferred on MDL courts. *See* 28 U.S.C. § 1407 (“[A] judge or judges to whom such [multidistrict] actions are assigned by the judicial panel on multidistrict litigation . . . may exercise the powers of a district judge in any district for the purpose of conducting pretrial depositions in such coordinated or consolidated pretrial proceedings.”); *see also U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 444 F.3d 462, 468-69 (6th Cir. 2006) (“A judge presiding over an MDL case therefore may compel production by an extra-district nonparty; enforce, modify, or quash a subpoena directed to an extra-district nonparty; and hold an extra-district nonparty deponent in contempt, notwithstanding the nonparty’s physical situs in a foreign district where discovery is being conducted.”); *In re Neurontin Mktg., Sales Pracs., & Prod. Liab. Litig.*, 245 F.R.D. 55, 58 (D. Mass. 2007) (“[T]he rationale underlying the MDL statute of ‘just and efficient’ resolution of pretrial proceedings requires the conclusion that Section 1407(b)’s grant of authority applies to both deposition subpoenas and documents-only subpoenas.”) (quoting *U.S. ex rel. Pogue*, 444 F.3d at 469 n.4).

B. This Court Reviews the Miami VA’s Objections Under an “Arbitrary and Capricious” Standard.

Courts have applied two differing standards have been utilized for reviewing the denial of *Touhy* requests. Some courts have concluded that the issue is governed by the application of the much more liberal discovery provisions contained in the Federal Rules of Civil Procedure, which tend to favor the allowance of such testimony. Others, however, have relied upon the higher “arbitrary and capricious” standard set forth in the APA.¹ The Eighth Circuit has not decided the issue, though the District of Minnesota has applied the Rule 45 standard without expressly addressing the dispute. *See Liptak v. Ramsey County*, No. 16-225 (ADM/JSM), 2016 WL 5662082, at *8 (D. Minn. Aug 24, 2016).

This Court should grant Defendants’ motion to compel the Miami VA under either standard. Here, Defendants address the “arbitrary and capricious” standard, because it is more deferential to the Miami VA. To the extent this Court concludes Rule 45 standards are applicable, the support for Defendants’ position is even stronger.

¹ Where the APA applies to an agency’s denial of discovery, enforcement of Defendants’ subpoena may be sought through a motion to compel; a separate, independent action is not required. *See United States Env’tl. Prot. Agency v. General Elec. Co.*, 197 F.3d 592, 599 (2d Cir.1999) (“[T]he APA allows the enforcement of a non-party *subpoena duces tecum* for discovery against the government through a motion to compel compliance.”); *see also Barnett v. Illinois State Bd.*, No. 02 C 2401, 2002 WL 1560013, at *1 (N.D. Ill. Jul. 2, 2002) (“[A] motion to compel directed against the [agency] does the job of bringing an APA ‘action’ before the court equally as well as, if not better than, a separate APA claim against the [agency].”) (internal citation omitted).

C. The Miami VA's Decision Not to Comply with Defendants' Subpoenas Is Arbitrary and Capricious and Violates the Federal Discovery Rules.

Under 5 U.S.C. § 301 (the “Housekeeping Act”), federal agencies are authorized to promulgate regulations regarding, among other things, the procedures to be followed when a party seeks the production of documents or witnesses for deposition. *See U.S. ex rel. Touhy v. Ragen*, 340 U.S. 462, 467-68 (1951).² The Housekeeping Act, however, “does not authorize withholding information from the public or limiting the availability of records to the public.” *Liptak*, 2016 WL 5662082, at *8. Thus, although federal agencies are entitled to establish certain standards and requirements to be adhered to in seeking the production of documents or witnesses, the agency is not permitted to deny such requests in an arbitrary or capricious manner. *See* 5 U.S.C. § 706(2); *see also Rhoads v. U.S. Dept. of Veterans Affairs*, No. 16-cv-01273-LJO-EPG, 2017 WL 1037616, at *3 (E.D. Cal. Mar. 17, 2017) (“[A] reviewing court may ‘hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.’”) (ellipsis in original); *Cabral v. U.S. Dept. of Justice*, 587 F.3d 13, 23 (1st Cir. 2009) (agency decision may be overturned if found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law”); *U.S. E.P.A.*, 197 F.3d at 599 (same); *Moore v. Armour Pharm. Co.*, 927 F.2d 1194, 1197 (11th Cir. 1991) (same).

² Such regulations are commonly known as “*Touhy* regulations.” *See In re Vioxx Prods. Liab. Litig.*, 235 F.R.D. 334, 343 (E.D. La. 2006).

In evaluating an agency's decision, the reviewing court reviews the administrative record to determine whether the decision "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Rhoads*, 2017 WL 1037616, at *3-4. The relevant factors as promulgated by the VA in its *Touhy* regulations are set forth in 38 C.F.R. § 14.804. They include, of relevance here, (1) the need to avoid spending government resources for private purpose and conserving the time of VA personnel for performance of their official duties, (2) whether the request is unduly burdensome or otherwise inappropriate under applicable rules, (3) whether the testimony or production of records is appropriate or necessary under the applicable rules, (4) whether the testimony or release of records could result in VA or federal government appearing to favor one litigant over another, or endorsing a position advocated by one party over another, (5) whether the request is within the authority of the party making it, and (6) whether the request is sufficiently specific to be answered. *See Rhoads*, 2017 WL 1037616, at *5-6.

In making their request to the Miami VA, Defendants noted these factors and explained how the information and testimony requested through the subpoena was consistent with those considerations. (Hulse Decl., Exs. 1-3.) Defendants explained that their requests are appropriate and sufficiently specific to be answered, will not create any appearance of favoritism, and will not create any undue burden, particularly since Defendants are offering to take the necessary depositions outside of business hours if necessary to accommodate an employee's schedule. *See id.* The Miami VA did not acknowledge Defendants' rationale in its response but, instead, and without detail, refused compliance based on boilerplate assertions of undue burden, the appearance of favoring

one litigant over another, and prohibitions against VA personnel offering “speculative” opinions. (Hulse Decl. Ex. 4.) None of these objections is accurate or applicable here.

As explained above, the information sought through Defendants’ subpoena is highly relevant and goes to the heart of Mr. Nugier’s claims. His surgery was performed at Miami VA. VA personnel were directly involved in providing his medical care, and are uniquely situated to provide relevant – and critical – factual information regarding the circumstances of his surgery and subsequent infection. This information is equally relevant to Nugier’s efforts to prove his claims and overcome Defendants’ defenses; thus, it is difficult to imagine how compliance with Defendants’ subpoena could be construed as favoring one litigant over the other. Moreover, the Miami VA failed to address – or even acknowledge – Defendants’ repeated offer to accommodate medical personnel’s work schedules, or to provide any rationale for its position that Defendants’ requests are unduly burdensome or otherwise inappropriate. *See Rhoads*, 2017 WL 1037616, at *7 (concluding that VA’s refusal to comply with subpoena was arbitrary and capricious where it failed to address “offer to accommodate VA employees’ work schedules and to consider the burden in light of other important factors”).

It is not sufficient for the Miami VA to “pay[] only lip service to the majority of factors,” as it has done here. *See id.* at *9 (citing *Ohio Health Corp. v. U.S. Dept. of Veteran Affairs*, No. 2:14-CV-292, 2016 WL 4660092, at *6-7 (S.D. Ohio Sept. 17, 2014)). Any alleged burden that would be imposed on the VA is far outweighed by the importance of the evidence Defendants seek. *See Williams v. C. Martin Co. Inc.*, No. CIV.A. 07-6592, 2014 WL 3095161, at *4-5 (E.D. La. July 7, 2014) (rejecting agency’s determination that

allowing deposition of employee would be unduly burdensome because “any burden on [the agency] is significantly outweighed by the importance of this evidence to the litigation”) (quoted in *Rhoads*, 2017 WL 1037616, at *7). The Miami VA failed to take these issues into account, and thus failed to adhere to its own regulations. Its refusal to comply with Defendants’ subpoena is arbitrary and capricious, and unsupportable under Rules 26 and 45.

CONCLUSION

For the foregoing reasons, the Miami VA’s objections to Defendants’ subpoenas for documents and deposition testimony should be overruled. This Court should order the Miami VA to comply fully with Defendants’ subpoenas by producing documents by the end of September and offering its witnesses for deposition before the fact discovery cutoff of October 16. In the alternative, if Defendants are going to be deprived of this discovery, the *Nugier* case should be de-designated as a bellwether because the parties will not be able to fully develop the necessary record concerning the facts of Mr. Nugier’s surgery and the causation of his alleged infection.

Dated: August 29, 2017

Respectfully submitted,

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